

## REMARKS

Favorable reconsideration is respectfully requested.

The claims are 1 to 6.

Claim 4 has been rejected as indefinite in the use of the term "can be". In reply, the term "can be" has been changed to "is", to advance prosecution. However, Applicants respectfully disagree that the term is indefinite since one of ordinary skill in the art could readily determine the scope of the claim.

Claims 1 to 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guy et al. (U.S. 3,906,086) in combination with Kreutner et al. (U.S. 5,869,479).

This rejection is respectfully traversed.

Guy describes a time-release pharmaceutical preparation containing aspirin as the active therapeutic agent.

Efletirizine is not mentioned and, in fact, Guy is completely focused on aspirin; no other active therapeutic agent is mentioned, or suggested. There is no generic or specific teaching or suggestion found in Guy which would direct one skilled in the art to use the specific product, efletirizine, required in the present claims.

Kreutner describes a method of relieving symptoms of rhinitis comprising administration of an antihistaminic effective amount of one or more histamine H1 receptor antagonists and an amount of one or more histamine H3 receptor antagonists. Efletirizine is cited in column 2 and claim 4 as being a histamine H1 receptor antagonist among 40 other histamine H1 receptor antagonists. Moreover, in the examples, the experimental data concern loratadine and descarboethoxyloratadine only; efletirizine is not exemplified despite the fact that the Official Action refers to Example 8.

The rejection is based on an improper hindsight reconstruction of the present invention by choosing from among the disclosed long lists of active ingredients in Kreutner to arrive at the inventive composition. There is no motivation from Kreutner to encourage a person of ordinary skill in the art to choose efletirizine as required in the present claims, from among the long list of

Kreutner.

The rejection has taken general disclosures from Guy's time release aspirin and Kreutner's decongestant out of context and combined several non-preferred features remote from the examples therein, to arrive at the present invention.

Claims 1 to 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S. 4,464,375) in combination with Kreutner.

Further, Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S. 4,464,375) in combination with Kreutner as applied to claims 1 to 5 above, and further in view of Guy.

These rejections are respectfully traversed.

Sunshine describes a pharmaceutical composition comprising caffeine and one or more analgesic agents or caffeine and an anti-inflammatory agent.

As correctly pointed out by the rejection, efletirizine is not mentioned in Sunshine. However, the rejection draws attention to the specific paragraph of column 16, lines 16 to 26 which discloses "when such long acting drugs are employed, it is often desirable to include an additional analgesia-enhancing amount of caffeine in the composition in sustained release form...". Efletirizine has no link with caffeine or with analgesia, so a person skilled in the art would not apply this especially focused disclosure to efletirizine.

The rejection employs impermissible hindsight analysis to derive the present invention from Sunshine and Kreutner and Guy. The rejection has "cherry picked" features from an throughout Sunshine and Kreutner and/or Guy to reach the target of the present claims.

Accordingly, the rejections on prior art are untenable and should be withdrawn.

Lastly, there is submitted herewith an Information Disclosure Statement enclosing references cited in the International Search Report which the Examiner has refused to consider, i.e. WO 98/41194 and EP 1118321.

Reference is made to the corresponding U.S. Patent 6,699,502 and U.S. Patent application 2002/0110596 in connection with WO 98/41194 (in French).

With regard to EP 1118321, it concerns a solid controlled release pharmaceutical composition for oral administration, which contains active ingredient, matrix-type excipient, enterosoluble polymer and soluble alkaline compound.

No further issues remaining, allowance of this application is respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact undersigned at the telephone number below.

Respectfully submitted,

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